

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

S.S., a Minor, by and through)	CASE NO. 8:13-cv-00143
Doran Schmidt, her natural mother and)	
Next friend, and DORAN SCHMIDT,)	
Individually,)	
)	
Plaintiffs,)	
)	
v.)	
)	
HEATHER RAMSEY, APRN-CNM, THE)	
MIDWIFE'S PLACE, LLC, and THE)	
BELLEVUE MEDICAL CENTER, LLC)	
)	
Defendants.)	

**BRIEF OF THE AMERICAN COLLEGE OF
OBSTETRICIANS AND GYNECOLOGISTS AS *AMICUS CURIAE* AS TO
DEFENDANTS' *DAUBERT* MOTION *IN LIMINE***

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ATTORNEYS FOR THE AMERICAN
COLLEGE OF OBSTETRICIANS AND
GYNECOLOGISTS AS *AMICUS CURIAE*

I. STATEMENT OF INTEREST OF ACOG AS *AMICUS CURIAE*

The issues presented in this case are of great importance to the American College of Obstetricians and Gynecologists (“ACOG”), its physician members, and the patients they serve. ACOG has a fundamental interest in keeping unfounded professional liability opinions and “junk science” out of the courtroom because of the prejudicial effect of such untested and unproven theories. The emphasis on evidence-based medicine has taken on new and greater importance as the environment of clinical practice grows more diverse, with increased access to more information by both physicians and patients and the changing allocation of resources. “Reading the Medical Literature,” ACOG. <http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature>, Exhibit 6 to Affidavit of Strunk. The quality of evidence proffered and admitted in professional liability litigation can directly and indirectly affect medical practices and the ability of obstetricians and gynecologists, among others, to provide care for patients, as well as affect the cost and availability of medical care to women and the entire population.

ACOG has a strong interest in this Court’s determination regarding the defendants’ motions in limine to exclude plaintiffs’ expert witness opinions relating to Craniocerebral Compression Ischemic Encephalopathy (“CCIE”) (Filing Nos. 146 & 160). This theory advanced by plaintiffs’ expert witnesses is new only in name and is not now and never has been supported by the scientific and medical literature. Accordingly, this Court is asked to play an essential role as gatekeeper by excluding unfounded expert testimony. The issues to be resolved in this case will have an immediate and lasting impact on medical practice and the health care of women in the State of Nebraska and beyond.

II. ACOG BACKGROUND

ACOG is a nonprofit, educational and professional organization founded in 1951 with over 58,000 current members, including 333 members in Nebraska. More than 90% of American board-certified obstetricians and gynecologists are members of ACOG. (Affidavit of Strunk, ¶ 5 & ¶ 7). As such, ACOG is the leading professional organization of physicians dedicated to the advancement of women's health care. (Affidavit of Strunk, ¶5).

ACOG works in the areas of continuing medical education, practice and research. (Affidavit of Strunk, ¶5). The objectives of ACOG are to:

- (1) Foster and stimulate improvements in all aspects of health care of women in the United States and globally,
- (2) Establish and maintain the highest possible standards for education,
- (3) Foster the highest standards of practice its relationship to the public welfare,
- (4) Promote high ethical standards in practice,
- (5) Promote publications, and
- (6) Encourage contributions to the medical and scientific literature.

(Affidavit of Strunk ¶ 6 & Ex. 1, The American College of Obstetricians and Gynecologists Bylaws, Amended February 2015).

ACOG's membership includes both specialists and subspecialists in the field of obstetrics and gynecology, which is a discipline dedicated to the broad, integrated medical and surgical care of women. Obstetrics and gynecology require extensive study and understanding of anatomy, reproductive physiology, endocrinology, and neurology, including the psychological, social, cultural, environmental and genetic factors that influence women's health care. (Affidavit of Strunk, ¶8).

ACOG works closely with numerous federal agencies, including the National Institute of Child Health and Human Development, U.S. Centers for Disease Control and Prevention, Office of Women's Health in the U.S. Department of Health and Human Services, the U.S. Food and Drug Administration, and various women's health coalitions. (Affidavit of Strunk, ¶9). ACOG primarily focuses in four areas:

- (1) Serving as a strong advocate for quality health care for women;
- (2) Establishing and maintaining the highest standards of clinical practice and education for its members;
- (3) Promoting patient education and stimulating patient understanding of, and involvement in, medical care; and
- (4) Increasing awareness among its members and the public of the changing issues facing women's health care.

(Affidavit of Strunk, ¶10). In order to facilitate these goals, ACOG keeps its members informed by providing current clinical guidelines and professional recommendations through its publications including Committee Opinions, Practice Bulletins, Technology Assessments and task force reports. *Obstetrics & Gynecology* (commonly known among professionals as the "Green Journal") is ACOG's official journal. The goal of the Green Journal is to promote excellence in the clinical practice of obstetrics and gynecology. It is one of the leading peer-reviewed, scientific and scholarly medical journals focused on women's health care. (Affidavit of Strunk, ¶11).

III. THE CAUSATION THEORY EXPRESSED BY PLAINTIFFS' MEDICAL EXPERT WITNESSES REGARDING CCIE IS NOT SUPPORTED BY THE SCIENTIFIC AND MEDICAL LITERATURE.

This case deals with issues and theories within the framework of ACOG's mission to promote women's health care in the field of obstetrics. Plaintiffs seek to advance an unaccepted

and unsubstantiated theory to lay jurors. Plaintiffs' expert witnesses express opinions as to the alleged cause of the minor plaintiff's condition, claiming it was due to Craniocerebral Compression Ischemic Encephalopathy ("CCIE"), which was allegedly caused by traumatic injury to the fetus' head as a result of the uterine contractile forces of labor. As noted, this theory expressed by plaintiffs' expert witnesses is not supported by the scientific and medical literature. ACOG is uniquely qualified to explain how the discipline of obstetrics and gynecology advances women's health care through the dissemination and application of scientifically-based guidelines, and peer-reviewed literature. (Affidavit of Strunk, ¶12).

By way of example, beginning in 1995, ACOG began developing practice guidelines derived from the best scientific evidence of clinical efficacy, as well as costs, resulting in evidence-graded recommendations. ACOG has thereby endeavored to improve the quality of health care, decrease cost, and, not incidentally, improve the quality of evidence offered in professional liability litigation. "Reading the Medical Literature," ACOG.

<http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature>,. As a result, ACOG has an extensive knowledge and understanding of peer-reviewed, scientifically-based literature describing the state of knowledge and accepted health care practices in the field of obstetrics and gynecology. (Affidavit of Strunk, ¶13 & Exhibit 6).

The theory of plaintiffs' expert witnesses in this case represent speculation and conjecture not based upon study, review and critical comment by those experts in the field, and are not based upon scientifically-acquired evidence. (Affidavit of Strunk, ¶21). Importantly, ACOG and the American Academy of Pediatrics published *Neonatal Encephalopathy and Neurologic Outcome*, Second Edition (2014). (Affidavit of Strunk at ¶ 16 & Exhibit 5). This 236-page

publication was developed by a task force comprised of ACOG physician members, physician members of the American Academy of Pediatrics, a PhD of the Centers for Disease Control and Prevention, and physicians of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and members of international ob-gyn societies and consultants after more than four years of intensive work. In all, there were 17 task force members and 88 consultants (physicians and PhDs) who collectively reviewed approximately 1,500 references as part of an extensive undertaking to analyze the applicable available evidence regarding neonatal encephalopathy, the central issue before this Court. Through this process, a goal of the task force was to summarize “the best available primary-source scientific data and expertise of highly qualified individuals who have been major contributors to the field.” (Task Force Report xviii). (Affidavit of Strunk at ¶ 16 & Exhibit 5)).

This study, review and compilation of “the best available primary-source scientific data and expertise” is important to the *Daubert* motions of the defendants pending before this Court, given the publication’s extensive review of current issues surrounding neonatal encephalopathy. The data and evidence are from studies reviewed and evaluated for quality according to the following method outline: from properly designed randomized controlled trials, evidence from well-designed controlled trials without randomization, evidence from well-designed cohort or case-controlled analytic studies, including from more than one center or research group, evidence from multiple time series, and opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert communities. (Affidavit of Strunk at ¶ 17 & Exhibit 5).

ACOG has provided the Court with this document, calling attention to select pages from the text, including the table of contents and index, to identify the wide range of topics, conditions and issues studied regarding neonatal encephalopathy. The novel theory expressed by plaintiffs’

expert witnesses regarding CCIE is not examined in this study because it is not supported in the scientific and medical literature. (Affidavit of Strunk at ¶ 18 & Exhibit 5).

IV. ACOG SUPPORTS THE *DAUBERT* PRINCIPLES.

ACOG recognizes the seminal decision of the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 2d 469, (U.S. Jun 28, 1993) (NO. 92-102) establishing standards for admissibility of expert witness testimony. Under *Daubert*, a trial judge has a duty to rigorously scrutinize evidence to determine whether it meets the requirements of Federal Rule of Evidence 702. Scientific, technical, or other specialized knowledge, to assist the trier of fact, must be based upon sufficient facts or data and must represent the application of reliable principles and methods applied to the facts of the case. The Supreme Court indicated that evidence based on innovative or unusual scientific knowledge may be admitted only after it has been established that the evidence is reliable and scientifically valid and that the trial court must serve as a gatekeeper to prevent "junk science" from entering the courtroom as evidence. *Daubert* outlined four considerations: testing, peer review, error rates, and acceptability in the relevant scientific community.

The defendants' expert witnesses in this case will examine in detail the application of these four factors as they test the proffered testimony of the plaintiffs' expert witnesses. It is ACOG's position that the novel theory of plaintiffs' expert witnesses dealing with CCIE is not recognized as tested, not subjected to meaningful peer-review, not authoritatively published and not accepted in the scientific community.

Further, an expert witness' personal, subjective view offered with the exclusion of accepted medical science does not meet the test of *Daubert*. The theory expressed by plaintiffs' expert witnesses dealing with CCIE is so devoid of a medical basis that it is not entertained

among the etiologies of neonatal encephalopathy discussed in the profession's scientific literature.

V. THE EFFECT OF "JUNK SCIENCE" ON THE PRACTICE OF MEDICINE

The unsupported causation theory advanced by plaintiffs' expert witnesses will have a significant impact on ACOG members in Nebraska and throughout the country. Obstetricians and non-physician maternity care providers deliver millions of babies in the United States each year. In 2012, there were close to 4 million births in the United States. The vast majority, 98.6%, of these births occurred in hospitals and were attended by physicians or nurse certified nurse midwives. (Affidavit of Strunk, ¶14 & Exhibit 2, National Vital Statistics Reports Vol. 62, No. 9, December 30, 2013, pp. 1, 2 & 8).

Despite advances in medicine and quality of care, pregnant women and their fetuses are faced with unavoidable risks inherent throughout pregnancy and in the physiologic processes of labor and delivery. Unfortunately, these risks will sometimes lead to maloccurrences, which are adverse or undesirable outcomes, despite adherence to applicable standards of care and in the absence of negligence. In personal injury litigation it would be inconvenient, at the least, for plaintiff to acknowledge the difference between maloccurrence and malpractice. As noted previously, medical maloccurrence is an undesirable, but recognized, adverse outcome unrelated to the quality of care, whereas malpractice contemplates proof of substandard practice which has caused harm. (Affidavit of Strunk ¶ 15, & Ex. 3, ACOG Committee Opinion, *Expert Testimony*, August 2007, Reaffirmed 2013).

To understand the scope of the adverse effect of the professional liability environment on the individual ob-gyn and the practice of women's health care, ACOG has conducted surveys of Fellows at approximately 2- to 4-year intervals since 1983. The 2012 ACOG Survey on

Professional Liability was the eleventh such survey. The entire population of practicing ACOG Fellows and Junior Fellows in the 50 states, the District of Columbia, and Puerto Rico were surveyed. The survey concluded:

Over half (51.1%) of ob-gyn survey respondents have made one or more changes to their practice as a result of the affordability or availability or both of professional liability insurance, and almost 58% (57.9%) have made one or more changes to their practice as a result of the risk or fear of professional liability claims or litigation. In both instances, ob-gyns significantly decreased the number of high-risk obstetric patients (18.1% and 27.4% respectively) and stopped performing or offering VBACs (13.5% and 18.9% respectively). In both instances, between 5% and 6% of respondents stopped practicing obstetrics altogether. The average age at which physicians stopped practicing obstetrics was 48.8 years, at one time the near midpoint of an obstetrician-gynecologist's professional career. The current medico-legal environment continues to deprive women of all ages, especially pregnant women, of their most educated and experienced women's health care physicians. Quality health care for women is negatively impacted through a diminution of obstetric services, a reduction in gynecologic surgery, and an increase in the practice of defensive medicine.

(Affidavit of Strunk ¶ 22, Ex. 4, 2012 ACOG Survey on Professional Liability).

[http://www.acog.org/-/media/Departments/Professional-](http://www.acog.org/-/media/Departments/Professional-Liability/2012PLSurveyNational.pdf?dmc=1&ts=20150401T1507176631)

[Liability/2012PLSurveyNational.pdf?dmc=1&ts=20150401T1507176631](http://www.acog.org/-/media/Departments/Professional-Liability/2012PLSurveyNational.pdf?dmc=1&ts=20150401T1507176631) Thus, given the adverse effect of professional liability litigation on medical practice and the availability of quality health care for women, ACOG has a strong interest in the matter presently before this Court. Simply put, the effect of junk science when permitted as evidence in medical liability lawsuits has an adverse impact on the availability and cost of medical care in the field of obstetrics and gynecology. (Affidavit of Strunk, ¶ 22).

Thus, there is a demonstrated trend of reduction in those services provided by experienced obstetricians-gynecologists as a result of the risk or fear of medical liability claims.

VI. ACOG’S PUBLICATIONS, GUIDELINES AND OTHER WORKS ARE FREQUENTLY RELIED UPON BY COURTS AS AUTHORITATIVE

ACOG has often provided *amicus* input in matters involving obstetric and gynecologic care. The materials submitted by ACOG have been cited frequently by the United States Supreme Court and other federal courts seeking authoritative medical information regarding health care for women. *See, e.g., Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG’s *amicus* brief extensively and referring to ACOG as among the “significant medical authority” supporting the comparative safety of the procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing ACOG’s *amicus* brief in assessing disputed parental notification requirement); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing “accepted medical standards” for the provision of obstetric-gynecologic services); *see also Gonzales v. Carhart*, 550 U.S. 124, 170-171, 175-178, 180 (2007) (Ginsburg, J., dissenting) (referring to ACOG as “experts” and repeatedly citing ACOG’s *amicus* brief); *Planned Parenthood Arizona, Inc. v. Humble*, 753 F.3d 905, 908 (9th Cir. 2014) (citing ACOG’s *amicus* brief in its discussion of the evidence-based regimen for medication abortion); *Planned Parenthood of Wisconsin, Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013) (citing ACOG’s *amicus* brief in evaluating the relative safety of outpatient medical procedures); *Greenville Women’s Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG’s guidelines and describing those guidelines as “commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of care for their patients”); *Stuart v. Camnitz*, 774 F.3d 238, 251-252, 254-255 (4th Cir. 2014) (citing ACOG’s *amicus* brief and committee opinion in its discussion of informed consent). (Affidavit of Strunk ¶ 19).

VII. ACOG IS A LEADER IN THE FIELD OF EDUCATION AND RESEARCH FOR OBSTETRICIANS AND GYNECOLOGISTS.

For more than 60 years, ACOG has provided worldwide influence and leadership in obstetrics and gynecology. Obstetricians and gynecologists look to ACOG for practice guidelines and scientific, peer-reviewed studies. (Affidavit of Strunk ¶ 20).

Expert witness medical opinions which are inconsistent with current medical science and not developed in accordance with scientific methodology have a deleterious effect on society. The admittance of such testimony as evidence in professional liability litigation tells physicians and other health care providers that science and good medical practice are not esteemed in our jurisprudence. Physicians have changed and will change their practices as a result of the risk or fear of professional liability litigation. This directly and indirectly diminishes obstetric and gynecologic services, and leads to wasteful practices of “defensive medicine.”

The novel CCIE theory of plaintiffs’ expert witnesses in this case is simply not supported by established, tested and peer-reviewed medical principles and science. (Affidavit of Strunk ¶ 21).

This is precisely the type of testimony that *Daubert* asserts should be excluded. Testimony based on speculation or conjecture is destructive of rational therapeutics and will ultimately have an adverse effect on public health.

CONCLUSION

The American College of Obstetricians and Gynecologists respectfully requests the Court to consider this *Amicus Curiae* brief and its Index of Evidence in support of defendants’ motion *in limine* to exclude the unsupported theory of Craniocerebral Compression Ischemic Encephalopathy offered by plaintiffs’ expert witnesses.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 2, 2015, I filed the forgoing with the Clerk of Court using the CM/ECF system, which sent notification of such filing to the following:

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And I hereby certify that I have mailed by United States Postal Service the document to the following non CM/ECF participant:

None.

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